REMARKS

This paper is intended as a full and complete reply to the Office Action dated July 30, 2009, having a shortened statutory period set to expire on October 30, 2009.

Claims 1-4, 6-10 and 22-24 are pending in the application.

Claims 1-4, 6-9 and 22-24 are currently amended in this response.

Claims 5 and 11-21 have been cancelled.

Specification

Applicants appreciate the withdrawal of the objection under 35 USC 132(a) due to the amendment filed June 3, 2009.

Claim Rejections – 35 USC §112

Applicants appreciate the withdrawal of the rejection of claims 1 and 22-24 under 35 USC 112, first paragraph, due to the amendment filed June 3, 2009.

Claims 1-4, 6-10 and 22-24 were rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point a distinctly claim the subject matter which applicant regards as the invention. The term "complete prescription history" in claims 1 and 22 was considered a relative term which renders the claim indefinite.

Claim 1 and 22 define the term complete prescription history as "all prescriptive medications purchased in the aggregate by the purchaser from all of said plurality of entities based on the pharmaceutical data." Further, the specification describes the complete prescription history at page 16, line 17 - page 17, line 7.

Claim 1 was rejected because the term "said transferred pharmaceutical computer data" had insufficient antecedent basis. Claim 1 has been amended to avoid the antecedent basis rejection.

Claims 2, 3 and 6 were rejected because the term "said selected prescriptive medication purchaser" lacked antecedent basis. Claims 2, 3 and 6 have been amended to avoid the antecedent basis rejection.

Claim 2, 3, 6 and 7 recite the limitation "said pharmaceutical computer data" as having insufficient antecedent basis. The claims have been amended to avoid the antecedent basis rejection.

Claims 2, 3, 4 and 6 recite the limitation "said prescriptive history" as having insufficient antecedent basis. The claims have been amended to avoid the rejection of insufficient antecedent basis.

Claim 7 recites the limitation "said prescriptive medication purchases" as having insufficient antecedent basis. The claim has been amended to avoid the rejection based upon lack of antecedent basis.

Claim 8 recites the limitation "said stored pharmaceutical computer data" as having insufficient antecedent basis. The claim has been amended to avoid the rejection based upon insufficient antecedent basis.

Claim 22 recites the limitation "said complete prescriptive history" as having insufficient antecedent basis. The claim has been amended to avoid the rejection based upon insufficient antecedent basis.

Claims 23 and 24 recite the limitation "the prescription history" as having insufficient antecedent basis. The claims have been amended to avoid the rejection based upon insufficient antecedent basis.

Claims 9 and 10 incorporate the deficiencies of claim 1 and 7, and thus, were also rejected. Claims 9 and 10 have been amended, as was claims 1 and 7, to avoid the dependency rejection.

For the reasons given above, Applicants respectfully request withdrawal of the rejection based upon 35 USC § 112, second paragraph, and allowance of the claims.

Claim Rejections – 35 USC §101

Claims 1-4, 6-10 and 22-24 were rejected under 35 USC § 101 because the claimed invention was directed to non-statutory subject matter. Particularly, the recited steps of independent claim 1 were considered to be merely providing respective computer

connections, obtaining and storing data, transferring data, and generating patterns that are not tied to another statutory class such as a particular device or transformation.

Applicants appreciate the opportunity to clarify the invention by adding a computer system to independent claims 1 and 22.

For the reasons given above, Applicants respectively request withdrawal of the rejection based upon 35 USC §101 and allowance of the claims.

Claims Rejections – 35 USC §103

Claims 1-4, 6-10 and 22 were rejected under 35 USC § 103(a) as being unpatentable over Cunningham (US 6,859,708) in view of Denny (US 6,687,676). Cunningham was cited to identify all elements of the claims, except Cunningham does not expressly disclose unaffiliated pharmacies, nor does Cunningham disclose a complete prescription history comprising all prescription medications purchased in the aggregate by said selected prescription purchaser from all of said plurality of affiliated and unaffiliated pharmacies, and further Cunningham does not disclose generating from said complete prescription history of said selected purchaser one or more patterns defined by the pharmaceutical data associated with the selected purchaser which patterns empower the identification of prescriptive drug abuse and the control thereof. However, it was stated in the Office Action that Denny discloses unaffiliated pharmacies and that a complete prescription history is provided in Denny. Thus, it was postulated that it would have been obvious to a person of ordinary skill in the art to include the aforementioned features of Denny within Cunningham. The motivation for doing so would have been to provide centralized information in order to prevent improper use of prescribed drugs and fraud.

Further, Claims 23 and 24 were rejected under 35 USC 103(a) as being unpatentable over Cunningham (US 6,859,780) in view of Denny (US 6,687,676) and further in view of Edelson et al. (US 5,737,539). Cunningham and Denny were cited as not expressly disclosing one or more patterns from the prescription history to indicate prescription duplication, multi-source prescription abuse, or combinations thereof. Edelson was cited as disclosing one or more patterns from the prescription history

indicating prescription duplication, multi-source prescription abuse or combinations thereof. Thus, at the time of the invention, it was believed to have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Edelson with Cunningham and Denny. The motivation for doing so would have been to control abuse by refusing to process the prescription.

The analysis to determine whether the claimed invention meets the statutory conditions for patentability under 35 U.S.C. §103 requires that "obviousness," which is a legal term of art, be evaluated in each individual situation. More specifically, under *Graham v. John Deere Co.*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966), obviousness must be determined based upon the following considerations:

> The scope and content of the prior art;
>
> The differences between the subject matter sought to be patented and the prior art;
>
> The time at which the invention was made;
>
> The level of skill of a person having ordinary skill in the art to which the invention pertains; and
>
> Objective evidence indicating obviousness or nonobviousness. i.e. evaluating whether the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art.

Claim 1 recites a method usable to track prescriptive medication and control drug abuse that includes providing computer connections to entities including both affiliated and unaffiliated pharmacies, obtaining and storing pharmaceutical data related to prescriptive medication purchases by a plurality of purchasers from both the affiliated and unaffiliated pharmacies, and selectively transferring the pharmaceutical data to at least one of the entities to obtain a complete prescriptive history for a selected purchaser. Claim 1 combines and utilizes data from the entities/pharmacies that are affiliated with one another (i.e., two locations within a pharmacy or hospital chain), as well as pharmacies/hospitals that are unaffiliated with one another. (Applicant's Specification, Paragraph [0061]). The prescriptive history is based on all medications purchased in the aggregate, by a selected purchaser, from all of the affiliated and unaffiliated pharmacies from the time the connection was made. The complete prescriptive history is then used to

generate patterns that flag prescriptive drug abuse, such as prescription duplication, multi-source prescription abuse, and similar patterns. (Applicant's Specification, Paragraph [0070])

Applicant's method is specifically adapted for tracking controlled substances, preventing abuse, and managing prescription information in the aggregate, through use of an independent "clearinghouse" of prescriptive information. Continuously updatable information from both affiliated and non-affiliated parties is thereby accessible, in real time, and in context. An unbiased method is thereby provided which prevents prescriptive drug abuse, medical complications and death, and saves billions of dollars in healthcare costs and related costs to third party providers, insurers, and governmental programs.

The cited references, Cunningham in view of Denny, neither alone, nor in combination, teach each element of the claimed invention.

Cunningham does not teach a system adapted for preventing prescriptive drug abuse and instead describes a system used to track product media, i.e. tracking a clinical trial and/or sample pharmaceutical products. Cunningham describes that prescribers are given encoded media, such as a magnetic card, which are activated by the prescriber through connection to a central computing station before distribution to a patient, who then exchanges the activated media at a pharmacy for corresponding products. (Cunningham, Column 2, Line 64 – Column 3, Line 34). After activation of the media, and after validation of the media and dispensation of product, a database records the transactions, enabling audit and accounting procedures, which facilitates replenishment of dispensed products and payment of fees. (Cunningham, Column 3, Lines 40-53).

Cunningham fails to teach using pharmaceutical data acquired through computer connections to various entities to obtain a complete prescriptive history for a purchaser. Cunningham describes only discrete tracking of individual transactions, such as activation, validation, and dispensation, to facilitate performance of specific and discrete responses to these individual transactions, such as replenishment of product and payment of reimbursement. Cunningham does not disclose or suggest obtaining a complete prescriptive history.

Cunningham further fails to teach or suggest generating patterns that flag rescriptive drug abuse. Cunningham instead describes use of an activated product medium as a prescription form indicating a product and quantity/dose, which is validated upon dispensation. The system described by Cunningham does not track or generate patterns of any kind, related or unrelated to drug abuse, and instead simply records individual pharmaceutical transactions.

Cunningham defines the level of skill of a person having ordinary skill in the art to which the claimed invention pertains, and clearly teaches away from the claimed invention. Cunningham is silent concerning the primary function of the claimed invention, namely, Cunningham does not provide a prescription history for preventing prescription drug abuse. Cunningham further teaches away from the claimed invention by specifically being adapted to be applicable to only a small, selected number of prescription drug users, namely, those involved in product or clinical trials for testing a drug's efficacy. (See, e.g., Cunningham, Figures 1-4 and 6). The claimed invention, conversely, provides a complete prescriptive history for preventing prescription drug abuse.

Edelson describes an electronic prescription creation system, which accesses remote databases to obtain formulary and patient history information. (Edelson, Abstract) A patient condition or problem is associated with each drug prescribed to memorialize a physician's intent and treatment objectives. (Edelson, Column 4, Lines 43-45).

Edelson fails to teach the elements of claims not taught by Cunningham and Denny. Specifically, Edelson fails to teach use of pharmaceutical computer data to obtain a complete prescriptive history of a purchaser, and further fails to teach use of the complete prescriptive history to generate patterns, which flag prescriptive drug abuse. Edelson instead describes obtaining discrete, individual items of information for the purpose of making decisions regarding which drugs to prescribe, and does not teach or suggest obtaining a complete prescriptive history of a purchaser for purposes of flagging and preventing prescriptive drug abuse.

Denny describes a prescription verification system for tracking prescription information and communicating this information. Edelson et al. describes a prescription creation system. There exists no basis to combine Cunningham, Denny and Edelson et al. There is no basis to combine Cunningham with a prescription creation system and a prescription verification system. The combination of Cunningham in association with creating a prescription system and verifying a prescription system is not what the present invention teaches. The attached affidavit from the inventors, Messrs. Anon and Bornfreund, explains why the cited references are not combinable.

The differences between the prior art and the present invention provide an additional secondary consideration of the nonobviousness of the invention. Cunningham tracks the efficacy of a product or clinical trial using media, and Denny describes a prescription verification system, and Edelson et al. describes a prescription creation system. Were the claimed invention to be practiced using the methodology defined by Cunningham and/or Denny and/or Edelson, the claimed invention would be inoperable for its intended purpose to prevent prescription drug abuse. Affidavit, p.4, ¶1.

The numerous secondary considerations cited in the attached affidavit of Messrs. Anon and Bornfreund illustrate the uniqueness and nonobviousness of the claimed invention.

A long felt need exists for a method for tracking prescriptive medication, to address and control prescription drug abuse and other related errors. This need has not been met, and could not be met, by existing systems such as those found in Cunningham, Denny and Edelson et al. See, Affidavit, p.1, ¶1 through p.2, ¶2.

A further secondary consideration that weighs in favor of nonobviousness of the claimed invention is the references known to those skilled in the art, Cunningham, Denny and Edelson et al., without such individuals recognizing the significance of the claimed invention. For example, the use of tracking clinical trials and tracking payment for prescription drugs is known, but use of a prescription history for preventing prescription drug abuse is unique and nonobvious in light of these teachings. *Id.*

Additionally, the failure of established competitors in a highly competitive market to create the present invention, despite the incentive to do so, further indicates the

nonobviousness of the claimed invention. The claimed invention is a significant advancement in the art that enhances the determination of a problem that may exist intentionally or unintentionally. This effective determination is critical, the claimed invention solving a problem that a competitive market has previously failed to solve. See, Affidavit, p. 2, ¶¶ 3-4.

Further, the claimed invention provides benefits not realized previously by known methodologies by quickly defining a prescription history and speeding the awareness of and prevention of prescription drug abuse. See, Affidavit, p. 1, ¶4.

The results obtained by the claimed invention are new and unexpected, and are suggested nowhere in the prior art. The cited references are silent concerning creation of a complete prescruiptive history and using this history to prevent prescription drug abuse. See, Affidavit, p. 4, ¶1.

A further secondary consideration of nonobviousness of the present invention is the knowledge used by those skilled in the art without such individuals recognizing the significance of the claimed invention. For example, the use of tracking clinical trials and tracking payment for prescription drugs is known, but use of a prescription history for preventing prescription drug abuse is unique and nonobvious in light of these teachings. See, Affidavit, p. 4, ¶2.

Additionally, the failure of established competitors in a highly competitive market to create the present invention, despite the huge social and economic incentives to do so, further indicates the nonobviousness of the claimed invention. The claimed invention is a significant advancement in the art that enhances the determination of a problem that may exist intentionally or unintentionally. This effective determination is critical, where the claimed invention solves a problem that a competitive market has previously failed to solve, or even recognize a solution. See, Affidavit, p. 4, ¶3.

Further, the present invention provides benefits not realized previously by known methodologies by quickly defining a prescription history and speeding the awareness of and prevention of prescription drug abuse. See, Affidavit, p. 4, ¶4.

The results obtained by the present invention are new and unexpected, and are suggested nowhere in the prior art. The cited references are silent concerning the creation of a complete prescription history and using this history to prevent prescription drug abuse. See, Affidavit, p. 4, ¶5.

Finally, the evaluation of the present invention as a whole, considering the claimed structure and/or methodology, as well as its properties and the problems solved, reveals a unique, nonobvious method. The prior art teaches away from the claimed invention, failing to describe obtaining a complete prescriptive history for preventing prescription drug abuse.

The evaluation of the claimed invention as a whole, considering the claimed structure and/or metholodgy, as well as its properties and the problem solved, reveals a unique, nonobvious method. The prior art teaches away from the claimed invention, failing to describe obtaining a complete prescriptive history for preventing prescription drug abuse.

Conclusion

In light of the above discussion, Applicant respectfully submits that the application now stands in prima facie condition for allowance and courteously requests that this application be advanced to issue. The Applicant is of the opinion that no fees are required. However, if fees are required, the Commissioner is hereby respectfully authorized to deduct such fees from Deposit Account Number 13-2166.

The Examiner is respectfully invited to call the Applicant's representative at 713-355-4200, to discuss any matters that may arise, where such discussion may resolve such matters and place this application in condition for allowance.

Respectfully Submitted,

Date: October 30, 2009

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Affidavit of Jesse J. Bornfreund and Jeffery A. Anon
concerning secondary considerations
illustrating the uniqueness and nonobviousness of the invention entitled
Controlled Substance Tracking System and Method

As a named inventor, I hereby declare that:

There are numerous secondary considerations illustrating the uniqueness and nonobviousness of the claimed invention.

More than 15 million Americans abused prescription drugs such as OxyContin, Ritalin, and Valium last year, and thousands died from overdoses. "Drug poisoning has become the second leading cause of death from unintentional injury, exceeded only by motor-vehicle crashes," said Dr. Leonard Paulozzi, a medical epidemiologist with the Injury Center at the Centers for Disease Control and Prevention (CDC).

But while the deaths are accidental, the behavior that causes them may not be: Many people who are addicted to painkillers engage in "doctor-shopping," described below, convincing multiple physicians to write them prescriptions. A CDC study in West Virginia found that 21% of people who died from prescription-drug overdoses had seen five or more different health-care providers for controlled substances in the prior year. See for example, Parade Magazine, October 4, 2009. Prescription painkillers have now surpassed heroin and cocaine as the leading cause of fatal overdoses per Dr. Paulozzi in *Pharmacoepidemiology and Drug Safety*. The rate of fatal overdoses is now about as high in rural areas — 7.8 deaths per 100,000 people — as in cities, where the rate is 7.9 deaths per 100.000 people, according to a paper Mr. Paulozzi published in 2008 in *Pharmacoepidemiology and Drug Safety*.

"The biggest and fastest-growing part of America's drug problem is prescription drug abuse," says Robert DuPont, a former White House drug czar and a former director of the National Institute on Drug Abuse. "The statistics are unmistakable." About 120,000 Americans a year go to the emergency room after overdosing on opioid painkillers, says Laxmaiah Manchikanti, chief executive officer and board chairman for the American Society of Interventional Pain Physicians.

An audit by the GAO of the government program Medicaid in five large states found about 65,000 instances of beneficiaries improperly obtaining potentially addictive drugs at a cost of about $65 million during 2006 and 2007 — including thousands of prescriptions written for dead patients or by people posing as doctors.

The GAO has also found about 65,000 cases where Medicaid beneficiaries visited six or more doctors and up to 46 different pharmacies to acquire prescriptions — this practice, known as "doctor-shopping", enables purchasers to exceed the legal limit of drugs. Further, the GAO has recently found sixty-five doctors or pharmacists writing or filling prescriptions after being banned from Medicaid, some for illegally selling such drugs. Still further, the GAO has recently found about 1,800 prescriptions written for dead patients and 1,200 prescriptions "written" by dead physicians.

A long felt need exists for a method for tracking prescription medication, to address and control prescription drug abuse and other related errors. This need has not been met by existing systems that simply track individual instances of prescription issuance or dispensing of a product. Adverse events related to prescription drugs are responsible for an estimated $75 billion in costs, per year, as of 2005.

By way of example of the unexpected results achieved by the present invention, in 2006, well-known conservative radio talk show host Rush Limbaugh surrendered to authorities for fraud in obtaining prescription drugs. Limbaugh had been "doctor-shopping" in various states to find doctors who would prescribe him painkillers at a rate to keep up with his addiction. The individual doctors unaware of the previously issued prescriptions by the other doctors and not having a means to detect dosage abuse or possible drug interactions issued additional prescriptions at Limbaugh's request. Another notable example of the unexpected results achieved by the present invention is pop star Michael Jackson who died earlier this year. Mr. Jackson's death has been attributed in part to a prescription drug over dose. Jackson's prescribing doctor stated that he was not aware that Jackson was also receiving medication from other doctors; if he was aware he might not have prescribed him the medication and dosage that he did. Had my claimed system been in place, the doctors and pharmacists would have quickly learned that both Limbaugh and Jackson were trying to manipulate their physicians to get multiple dosages of prescription medications and the present invention would have blocked their attempt. These notorious and publicized situations illustrate that the results achieved by the present invention are unexpected.

It is estimated that a reduction in prescriptive medication abuse (intentional or unintentional) and related errors by as little as 15% can save as much as $15 billion annually. Adverse drug events increase a patient's health risks and decrease medical efficiency. A patient might visit one doctor for a particular ailment and get a prescription, and later that week visit a second doctor for a different ailment, and the second doctor might also prescribe a medication. If the second doctor is not made aware of the first prescription that was issued to the patient, he might prescribe a medication that has an adverse reaction to the first medication thereby putting the patient's health at risk. With the claimed invention, the second doctor is automatically made aware of the patient's drug history and would consider that information in determining which medication to prescribe. The claimed invention would not only lower health risks to patients but also reduce healthcare costs and efficiency by helping to eliminate patient hospital visits for adverse drug events.

Pharmaceutical companies are aware of the long felt need to overcome the Herculean problem of simply making the relevant people aware of the medications that are being taken. The pharmaceutical companies know that the medications that they produce and distribute are potential killers, if taken inappropriately. Particularly, the AstraZeneca pharmaceutical group of companies warns, "Be sure to tell your doctor if you are taking any prescription medications..." A more complete excerpt from their website is stated below:

> ... there is a chance of having a drug interaction while taking CRESTOR if you are also taking other medicines. Be sure to tell your doctor if you are taking any prescription medications ... While you are taking CRESTOR, don't start taking any of these medicines without checking with your doctor first. If you aren't sure if you're taking any of these medicines, be sure to ask your doctor or pharmacist. [See, attached Exhibit A or www.crestor.com].

Other sources make similar statements reflecting the continuing long felt need and unobviousness of the present invention. The MedlinePlus® website states, "be sure to tell your doctor about **all** the medications you are taking ... [and even] tell your doctor what herbal products you are taking..." A more complete excerpt from their website is stated below:

> ...tell your doctor and pharmacist if you are allergic to toremifene, or any other medications. Tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, and nutritional supplements you are taking or plan to take ... Your doctor may need to change the doses of your medications or monitor you carefully for side effects. Many other medications may also interact with toremifene, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list. [See, attached Exhibit B or www.nlm.nih.gov/medlineplus/print/druginfo/meds/a608003.html].

Adverse drug events are responsible for billions of dollars in healthcare cost each year, and there is an overwhelming long felt economic and social need to reduce this unnecessary cost. Each year prescription drug related problems cost an estimated $75 billion and injure or kill almost 800,000 people. According to the Institute of Medicine in July 2006, there are 1.5 million preventable adverse drug events that occur in the United States each year. With the present invention, most of these would not occur. Studies show that each patient who experiences an adverse drug event costs between $4,500 and $10,000 per event. On average this figure translates into an estimated cost of $5.6 million per year per hospital. Much of the non-medical use of prescription drugs is realized through emergency department visits at hospitals and clinics. Research shows that sharing prescription drug information electronically within hospitals may decrease adverse drug events by as much as 84%. Implementation of the present invention will save billions of dollars in healthcare costs annually, and directly help to fulfill the economic need to reduce healthcare costs. Had the present invention been obvious or anticipated by prior art, the economic need for it would have already been exhausted by others.

The differences between the prior art and the present invention provide an additional secondary consideration of the nonobviousness of the invention. Cunningham tracks the efficacy of a product or clinical trial using media, and Denny describes a prescription verification system, and Edelson et al. describes a prescription creation system. Were the claimed invention to be practiced using the methodology defined by Cunningham and/or Denny and/or Edelson, the claimed invention would be inoperable for its intended purpose to prevent prescription drug abuse.

A further secondary consideration of nonobviousness of the present invention is the knowledge used by those skilled in the art without such individuals recognizing the significance of the claimed invention. For example, the use of tracking clinical trials and tracking payment for prescription drugs is known, but use of a prescription history for preventing prescription drug abuse is unique and nonobvious in light of these teachings.

Additionally, the failure of established competitors in a highly competitive market to create the present invention, despite the huge social and economic incentives to do so, further indicates the nonobviousness of the claimed invention. The claimed invention is a significant advancement in the art that enhances the determination of a problem that may exist intentionally or unintentionally. This effective determination is critical, where the claimed invention solves a problem that a competitive market has previously failed to solve, or even recognize a solution.

Further, the present invention provides benefits not realized previously by known methodologies by quickly defining a prescription history and speeding the awareness of and prevention of prescription drug abuse.

The results obtained by the present invention are new and unexpected, and are suggested nowhere in the prior art. The cited references are silent concerning the creation of a complete prescription history and using this history to prevent prescription drug abuse.

Finally, the evaluation of the present invention as a whole, considering the claimed structure and/or methodology, as well as its properties and the problems solved, reveals a unique, nonobvious method. The prior art teaches away from the claimed invention, failing to describe obtaining a complete prescriptive history for preventing prescription drug abuse.

Signature: _____
JEFFERY A. ANON

Date: 10/29/09

STATE OF TEXAS §
COUNTY OF HARRIS §

BEFORE ME, the undersigned authority, on this 29 day of October 2009 personally appeared JEFFERY A. ANON known to me to be the person whose name is subscribed to the foregoing instrument and acknowledged to me that he executed the same of his own free will for the purpose and consideration therein expressed.

[SEAL] KRISTINE TROGER
Notary Public, State of Texas
My Commission Expires
MARCH 22, 2010

Kristine Troger
Notary Public in and for
the State of Texas

Signature: _____
JESSE J. BORNFREUND

Date: 10/29/09

STATE OF Washington §
COUNTY OF King §

BEFORE ME, the undersigned authority, on this 29th day of October 2009 personally appeared JESSE J. BORNFREUND known to me to be the person whose name is subscribed to the foregoing instrument and acknowledged to me that he executed the same of his own free will for the purpose and consideration therein expressed.

[SEAL]

ANDREW M DEPAOLA
Commission Expires
NOTARY PUBLIC
JULY 01, 2013
STATE OF WASHINGTON

_____
Notary Public in and for
the State of Washington